

# Notice of Allowability

Application No.

10/738,439

Examiner

David A Reifsnyder

Applicant(s)

DOLECEK ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed on March 31, 2004 and Examiner Interview of December 9, 2004.
2. ☒ The allowed claim(s) is/are 10-32 (renumbered as claims 1-23).
3. ☒ The drawings filed on 17 December 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 3/31/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

## **ELECTION/RESTRICTION AND EXAMINER'S AMENDMENT**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to a system for the production of a blood component ,  
classified in class 210, subclass 380.1.
- II. Claims 10-32, drawn to a method for producing a blood component,  
classified in class 210, subclass 782.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the instantly claimed process as claimed can be practiced by a materially different apparatus such as one which does not include the dispenser disposed outside the centrifuge and/or the mixing nozzle.

Because Inventions I and II are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the

search required for Invention I is different from the search required for Invention II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Jeffrey J Hohenshell on December 8, 2004 an election was made without traverse to prosecute the invention of Group II, claims 10-32.

Claims 1-9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in an telephone interview with on Jeffrey J Hohenshell on December 8, 2004.

During the telephone interview the following things were agreed to be done by  
Examiner's Amendment:

It was agreed to update the continuing data in the cross-reference to the related application section of the specification.

It was agreed to cancel claims 1-9 drawn to an invention non-elected without traverse.

It was agreed to amend claim 10 to overcome an antecedent basis problem, by adding the word ---the--- before the recitation of "one or more medicinal material" on the second to last line of claim 10.

It was agreed to amend claim 30 by deleting the instantly claimed medicinal materials that could not come from a patient as required. See the amendment to claim 30 below.

The application has been amended as follows:

***In the Specification***

Paragraph [0001] of the specification has been amended to show that parent application Ser. No. 09/832,517 has issued as U.S. Pat. No. 6,719,901.

***CROSS-REFERENCE TO RELATED APPLICATIONS***

[0001] This application is a Continuation application of U.S. patent application Ser. No. 09/832,517, filed Apr. 9, 2001, now issued as U.S. Pat. No. 6,719,901 which is a Continuation-in-Part of U.S. patent application Ser. No. 09/063,338, filed Apr. 20, 1998, now issued as U.S. Pat. No. 6,444,228, which is a Continuation-in-Part of U.S. patent application Ser. No. 08/640,278, filed Apr. 30, 1996, now abandoned. The disclosure of each of the above patent applications is specifically incorporated herein by reference in its entirety.

***In The Claims***

Claims 1-9 have been canceled.

Claim 10. (currently amended) A method of producing a blood component composition, comprising:

providing an anticoagulated blood sample having multiple inactive components from a patient;

centrifuging the blood sample to separate said inactive blood components;

combining a first portion of one of the separated inactive blood components with an activation agent to form a clot containing thrombin;

filtering the thrombin from the clot;

combining one or more medicinal materials with a second portion of the separated inactive blood component; and

combining the thrombin and the second portion of the separated inactive blood component comprising the one or more medicinal materials to produce the blood component composition.

Claim 30. (currently amended) The method of claim 22, wherein the medicinal material is selected from the group consisting of ~~drugs, analgesic compounds, antibacterial compounds, antifungal compounds, anti-inflammatories, antiparasitic compounds, antiviral compounds, anticancer compounds,~~ genetic agents, enzyme

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~~inhibitors, glycoproteins, growth factors, hormones, steroids, glucocorticosteroids,~~  
~~immunomodulators, immunoglobulins, minerals, neuroleptics,~~ proteins, peptides,  
~~lipoproteins, tumoricidal compounds, tumorstatic compounds, toxins,~~ vitamins,  
bone, gelatin, and collagen, ~~carbohydrates and starches~~.

### REASONS FOR ALLOWANCE

The main reasons for allowance of claims 10-21 is the method of producing a blood component composition, comprising: providing an anticoagulated blood sample having multiple inactive components from a patient; centrifuging the blood sample to separate said inactive blood components; combining a first portion of one of the separated inactive blood components with an activation agent to form a clot containing thrombin; filtering the thrombin from the clot; combining one or more medicinal materials with a second portion of the separated inactive blood component; and combining the thrombin and the second portion of the separated inactive blood component comprising the one or more medicinal materials to produce the blood component composition.

The main reason for the allowance of claims 22-32 is the method of producing a blood component composition, comprising: providing an anticoagulated blood sample having multiple inactive components from a patient; centrifuging the blood sample to separate said inactive blood components; combining a first portion of one of the separated inactive blood components with an activation agent to form a clot containing thrombin; filtering the thrombin from the clot; providing a medicinal material obtained

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from the patient; combining the medicinal material with a second portion of the separated inactive blood component; and combining the thrombin and the second portion of the separated inactive blood component comprising the medicinal material to produce the blood component composition.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Baugh et al. who discloses a system and method for the production of autologous platelet gel.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Reifsnyder whose telephone number is (571) 272-1145. The examiner can normally be reached on M-F 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda M Walker can be reached on (571) 272-1151. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
David A Reifsnyder  
Primary Examiner  
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DAR